

REMARKS

This invention relates to polycyclic nucleotide xanthine phosphodiesterase V inhibitors, processes for their preparation and uses to treat various disease states.

Entry of this Amendment is requested as it either places at least some of the claims in condition for allowance or in better condition for appeal.

This Amendment is accompanied with a Notice of Appeal.

This Amendment cancels claims 43 and 44 and replaces them with new independent claims 45, 46, 47, 50 and 51. Claims 45 and 46 most closely parallel former claims 43 and 44. These claims have been amended to remove several issues, which caused these claims to be rejected under 35 USC 112, second paragraph; *viz.*, these claims and the claims that depend from these claims do not contain the term "thioalkyl" and the alternative definitions for R⁵⁰, R⁵¹ and R⁵². It is urged that these claims are free from issues under 35 USC 112.

Claims 47 and 50 find support in original claims 1 and 40. These claims contain the term "thioalkyl" and the alternative definitions for R⁵⁰, R⁵¹ and R⁵². Claims 48 and 49 are directed to pharmaceutical compositions and a method of use for this subset of claims. These claims find support in claims 41 and 37 respectively. Thus, no new matter or new issue is created by these claims. Moreover, as the scope of the claim has not been narrowed, the application of the doctrine of equivalents is not affected.

Claim 51 is essentially former claim 27 written in independent form with the replacement of the terms “-COOH” and “ester” with the term “-C(O)OR⁵⁰”. As this new term has support in original claim 1 and is currently used, for example, in claims 44 and 45. Thus, no matter or new issue is created by the addition of this claim. The purpose of this change is to find an alternative expression for the term “ester”, which the Examiner found objectionable.

Authorization

The Commissioner is authorized to charge a two month extension of time and the fees associated with adding two independent claims in excess of three, one additional dependent claim, and any other fee associated with this Amendment to render the Amendment timely filed to Deposit Account No. 19-0365.

Claims 2-12, 27-30, 34, 35, 37, 39 and 41 to 44 stand rejected under 35 USC 112, second paragraph, for allegedly being indefinite. In view of the amendments to the claims and for the following reasons, reconsideration and withdrawal of this rejection are requested.

Regarding point 1, the choice of Y being $-(R^{23})(R^{24})N(H)-$ has been corrected. Applicants thank the Examiner for bringing this typographical error to their attention and apologize for failing to correct it in the previous Amendment.

Regarding the items in point 2, it urged that the term “thioalkyl” is definite since one skilled in the art upon reading the specification would understand that this term is a HS-alkyl-, or i.e. a mercapto group that is attached to an alkyl substituent. Accordingly, withdrawal of this objection is requested.

The test for indefiniteness as annunciated by the Federal Circuit is whether one skilled in the art would understand the scope of the claim when read in light of the specification. *Othrokinetic Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081 (Fed. Cir. 1986); *Hybritech Inc. v. Monoclonal Antibodies, Inc.* 231 USPQ 81, 88 (Fed. Cir. 1986). It should be noted that *In re Zletz*, 13 USPQ2d, 1320 (Fed. Cir. 1989), cited in the rejection, does not alter this test and the issue decided therein is not germane to this issue as it relates to the matter of claim interpretation before the Office. *Id.* at 1321-22.

Through out the definition section it is clear that the second group is the one onto which the first group is substituted. For example the term “hydroxyalkyl” is defined on page 13 as “a substituted hydrocarbon chain, preferably, an alkyl group, having at least one hydroxyl substituent” and the term “alkoxy” is defined as “an oxygen atom bonded to a hydrocarbon chain, such as an alkyl or alkenyl group.” See also the definitions for “carboxylalkyl”, “aminoalkyl” and “alkylamino”. Thus, in view of the foregoing, it is clear that “thioalkyl” refers to an alkyl group that is substituted with a thio group. Given that there is no other substituent on the sulfur, one would assume that a hydrogen would be attached to satisfy the valence requirements.

In response to this argument, the rejection argues a “parade of horrors” of alternative definitions which might be encompassed by the term “thioalkyl”. Again, Applicants argue for the reasons stated above, that upon reading the specification, one skilled in the art would recognize the “thioalkyl” as being “mercaptoalkyl”. From the specification, it is clear that Applicants are following

the convention in the art that the second group is the one to which the first group is attached. In order to complete the valence on the sulfur atom, one would assume that it would be a hydrogen atom. Hence, upon reading the specification, a skilled practitioner would understand the substituent to be HS-alkyl-.

Regarding point 3, Applicants again urge that the claims, as previously presented, are definite for reasons of record. However, Applicants have recast the claims so that the structures are presented as an independent claim, thus avoiding the issue.

Likewise, as the claims no longer recite the term "ester", the issue raised in point 4 is moot. Again, Applicants do not agree with the position taken in the rejection for reasons of record, but have amended the term in order to advance prosecution.

Regarding point 5, Applicants urged that the formula now recited in independent claim 51 is definite as one skilled in the art would understand that R^{11} and R^{12} supply the missing group on $(CH)_n$ or $(CH)_m$ in the ring. Hence, reconsideration of this issue is requested.

The Examiner urges that the material in the parentheses is not correct because there only be three bonds to carbon contained in the parentheses. Applicants respectfully disagree.

Upon reading the structure, one skilled in the art would understand that R^{11} and R^{12} supply the missing substituent. He or she would realize that R^{10} and R^{11} would have to be attached on a ring carbon atom and, as defined, this

would have to be $(CH)_n$ or $(CH)_m$. Applicants know of no reason that hydrogen cannot be a substituent and the examples would confirm that this could be the situation. Hence, it is urged that this structure is complete.

Applicants urge that the new claim language for the situation where "R¹⁰ and R¹¹ with each other and the carbon atom of the ring to which they are attached, form an optionally substituted bi- or tri-cyclic ring system of from 8 to 12 members, including from 0 to 4 hetero atoms" is definite. Hence, it is believed the issue raised in points 6 and 7 is moot.

Claims 2 to 12, 22, 23, 27 to 29, and 41 to 43 stand rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10 and 11 of US 6,821,978. In view of the fact that Applicants filed a certificate of correction in order to remove tetrahydropyranyl from claims 10 and 11 of said US patent (see appendix A), it is urged that this rejection is moot as there is no longer overlap. Accordingly, withdrawal of this rejection is requested.

It is believed that this application is now in condition for allowance and an early notice to that effect is earnestly solicited. If, however, there remains an issue outstanding, the Examiner is invited to contact the undersigned for its prompt resolution.

Favorable action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Mark W. Russell', is written over a horizontal line.

Mark W. Russell
Registration No. 37,514
Attorney for Applicants
Tel: 908-298-5024
Fax: 908-298-5388